

“pH 5.5” for consistency in presentation of the pH values. No new matter is added by way of claim amendments.

Claims 29-48 and 85-130 are now pending in the application. Reconsideration of the claims in view of the amendments and remarks is respectfully requested. The Examiner’s remarks in the Office Action are addressed below in the order set forth therein.

Formal Matters

The Office Action states that the declaration is defective because it indicates that the above-identified application incorrectly claims the benefit of a provisional application under 35 U.S.C. §120. Applicants wish to thank the Examiner for bringing this defect to their attention. A Substitute Declaration showing the correct claim for this priority document under 35 U.S.C. §119(e) will be submitted concurrently with the next communication to the Examiner. Upon its submission, the Examiner is respectfully requested to make the Substitute Declaration of record in the above-identified application.

The Rejections of the Claims Under 35 USC §112, Second Paragraph, Should Be Withdrawn

Claims 29-48 and 85-112 were rejected under 35 USC §112, second paragraph, as being indefinite. Specifically, the Office Action states that claims 29-48 and 85-112 are indefinite because of the use of the terms “at least about pH 5.5” and “at least about 12 mg/ml.” This rejection is respectfully traversed.

The Office Action states that the use of the phrase “at least about” in the context of these claims renders the claim indefinite, because it is unclear what pH the composition has. The Examiner reasons that “the composition can have a pH greater than 5.5 as to ‘at least’, but it can also have a pH less than 5.5 as to ‘about’” (Office Action mailed May 31, 2002, at page 3, item 5). Similarly, the Examiner reasons that the composition can have IGF-I or IGF-I analogue present at a concentration “greater than 12 mg as to ‘at least’, but it can also be less than 12 mg as to ‘about’” (Office Action, at

page 3, item 5). Applicants maintain that for reasons already of record, and further in view of the following reasons, the phrase “at least about” is definite in the context of the presently claimed invention.

The term “about” refers to the ability to measure a particular quantity. In the context of the claims at issue, “about” refers to the ability to measure the pH of the claimed compositions, and the ability to measure the concentration of IGF-I or IGF-I analogue in the claimed compositions. The term “about” has long been accepted as a way to define a numerical quantity in a claim. One of skill in the art readily recognizes that a phrase such as “about pH 5.5” means that the pH can be less than 5.5 as long as it is *about* pH 5.5. Thus, a measured pH value of, for example, pH 2.0 would not be about pH 5.5. Similarly, Applicants contend that one of skill in the art readily recognizes that the phrase “about 12 mg/ml” means that the concentration of IGF-I or IGF-I analogue in the claimed composition can be less than 12 mg/ml as long as it is *about* 12 mg/ml. By the Examiner’s own admission, the use of “about” in the context of a range of numerical values is acceptable claim language and does not render a claim indefinite. See the Office Action mailed May 31, 2002, at item 6, where the Examiner has suggested amending claims to recite a range of arginine concentrations or pH concentrations of “about ... to ... ”.

Further, Applicants respectfully note that the phrase “at least” is acceptable terminology when trying to define the lower limit for a numerical value. Thus, for example, where the numerical value is “X”, the adjectival phrase “at least X” clearly means that the value must be equal to X or greater.

As previously made of record, words such as “about” are often used in claims to prevent a potential infringer from avoiding literal infringement by making minor modifications. In the case of the compositions set forth in the pending claims, recitation of a pH of “at least about pH 5.5” means that to literally infringe the claimed composition, an accused infringer’s composition must meet all of the claim limitations, including the limitation of having a pH of *about* pH 5.5 *or greater*. Similarly, recitation of a concentration of “at least about 12 mg/ml” means that to literally infringe the claimed composition, an accused infringer’s composition must meet all of the claim

limitations including the limitation of having a concentration of IGF-I or IGF-I analogue of *about 12 mg/ml or greater*. Applicants respectfully submit that these claims are definite.

In addition, the Federal Circuit has ruled that the term “exceeding about” is definite. The presently rejected term “at least about” is similar to this claim element, which was subject to an indefiniteness rejection that was overturned by the Federal Circuit in *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). The claims of U.S. Patent No. 3,953,566 to Gore were directed to processes for stretching highly crystalline, unsintered poly(tetrafluoroethylene) (PTFE). The process included the step of stretching an unsintered shaped article consisting essentially of highly crystalline PTFE “at a rate *exceeding about 10% per second*” (claim 1; emphasis added). Dependent claims further recited the limitation of expanding the shaped article such that the final length in the direction of expansion was “*greater than about twice the original length*,” or “*greater than about five times the original length*” (claims 17 and 19; emphasis added). In *Gore* the lower court had held that the stretch rate “exceeding about 10%” was indefinite, as a formula for calculating stretch rate of the polymer was not provided and one of skill in the art would not know if the rate exceeded about 10%. The Federal Circuit overturned the lower court’s ruling of indefiniteness, reasoning that:

The use of “stretching . . . at a rate exceeding about 10% per second” in the claims is not indefinite. Infringement is clearly assessable through use of a stopwatch. No witness said that could not be done. *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983)

Similarly, in the present case, the rejected term “at least about” is definite because one of skill in the art can readily determine if the pH of a composition is *at least about* pH 5.5 or if a composition has IGF-I or IGF-I analogue present at a concentration of *at least about* 12 mg/ml. For example, the former can be measured using a pH meter or similar device, and the latter can be measured using, for example, UV spectroscopy with the known IGF-I absorption coefficient as taught in Applicants’ specification.

The Examiner is reminded that Applicants can be their own lexicographers “so long as the terms are not used in ways that are contrary to accepted meanings in the art” (MPEP §2173.01). Further, “a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought” (MPEP §2173.01, citing to *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971)). In the present case, the use of the phrase “at least about” in the context of numerical pH and concentration ranges is a well-accepted practice for defining the limits of a range. Further, use of relative terminology is acceptable according to MPEP §2173.05(b) so long as one of skill in the art would understand what is claimed. Applicants respectfully submit that one of skill in the art would understand both the use of the term “about” and the use of the phrase “at least about” in the context of the numerical pH and concentration ranges recited in these claims. In view of this and the foregoing arguments, Applicants respectfully submit that these claims are definite, and this rejection of the claims under 35 USC §112, second paragraph, should be withdrawn.

Claim 35 was rejected for being indefinite because of the use of the term “from about ... to about ...”. Claims 35-39, 88-92, and 102-106 have been amended, as suggested by the Examiner, to use the term “about ...to ...”. Thus these claims now recite a molar concentration range “of about ... to about ...” (claims 35-37, 88-90, 102-104) or a pH in a range “of about ... to about ...” (claims 38, 39, 91, 92, 105, and 106). Applicants respectfully submit that these claims are definite, and this rejection of the claims under 35 USC §112, second paragraph, should be withdrawn.

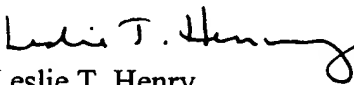
CONCLUSION

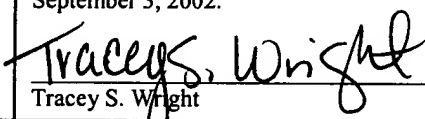
In view of the above amendments and remarks, Applicants submit that the rejection of the claims under 35 USC §112, second paragraph, is overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,


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Version with Markings to Show Changes Made:

In the Claims:

Please amend the claims to read as follows:

31. (Twice amended) The composition of claim 29, wherein said solubilizing compound is selected from the group consisting of arginine, N-acetyl-arginine, a dipeptide containing arginine, and a tripeptide containing arginine, wherein said dipeptide or said tripeptide increases solubility of said IGF-I or analogue thereof at a pH of at least about pH 5.5.

35. (Amended) The composition of claim 34, wherein said arginine is present in a molar concentration range [from]of about 10 mM to about 1 M.

36. (Amended) The composition of claim 35, wherein said arginine is present in a molar concentration range [from]of about 15 mM to about 500 mM.

37. (Amended) The composition of claim 36, wherein said arginine is present in a molar concentration range [from]of about 20 mM to about 200 mM.

38. (Amended) The composition of claim 34, wherein said pH is in a range [from]of about pH 5.5 to about pH 9.0.

39. (Amended) The composition of claim 38, wherein said pH is in a range [from]of about pH 5.7 to about pH 6.3.

46. (Twice amended) A composition comprising:

(a) biologically active insulin-like growth factor-1 (IGF-I) or biologically active analogue thereof having an amino acid sequence that shares at least 70% sequence identity with the amino acid sequence for human IGF-I, wherein said IGF-I or analogue thereof is present at a concentration of at least about 12 mg/ml when said composition is at a temperature of about 4°C;

(b) a solubilizing compound selected from the group consisting of arginine, N-acetyl-arginine, a dipeptide containing arginine, a tripeptide containing arginine, and guanidine

hydrochloride, wherein said dipeptide or said tripeptide increases solubility of said IGF-I or analogue thereof at a pH of at least about pH 5.5; and

(d) a buffer such that the composition has a pH of about pH 5.5 to about pH 9.0.

88. (Amended) The composition of claim 87, wherein said arginine is present in a molar concentration range [from]of about 10 mM to about 1 M.

89. (Amended) The composition of claim 88, wherein said arginine is present in a molar concentration range [from]of about 15 mM to about 500 mM.

90. (Amended) The composition of claim 89, wherein said arginine is present in a molar concentration range [from]of about 20 mM to about 200 mM.

91. (Amended) The composition of claim 87, wherein said pH is in a range [from]of about pH 5.5 to about pH 9.0.

92. (Amended) The composition of claim 91, wherein said pH is in a range [from]of about pH 5.7 to about pH 6.3.

102. (Amended) The composition of claim 101, wherein said arginine is present in a molar concentration range [from]of about 10 mM to about 1 M.

103. (Amended) The composition of claim 102, wherein said arginine is present in a molar concentration range [from]of about 15 mM to about 500 mM.

104. (Amended) The composition of claim 103, wherein said arginine is present in a molar concentration range [from]of about 20 mM to about 200 mM.

105. (Amended) The composition of claim 101, wherein said pH is in a range [from]of about pH 5.5 to about pH 9.0.

106. (Amended) The composition of claim 105, wherein said pH is in a range [from]of
about pH 5.7 to about pH 6.3.